UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON

IN RE DIGITEK®
PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER #49
(Memorandum Opinion and Order re Request for *Lone Pine* Order)

Pending is defendants' motion for entry of a *Lone Pine* case management order [Docket 200] and their supplemental motion modifying the relief sought from that order [Docket 205].

Subsequent to a timely response and reply being filed, the motion was taken under advisement pending completion of basic fact discovery in Group 1 cases. In accordance with the extensions of PTO #45, that discovery was to conclude by December 7, 2009. The matter is now ripe for disposition. I **DENY** the motions without prejudice.[1]

I.

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[1]The concept of a "*Lone Pine* order" originated from the unpublished decision of a New Jersey state court issuing a case management order in *Lore v. Lone Pine Corp.*, 1986 WL 637507 (Nov. 18, 1986). The plaintiffs in that case had sued over 400 defendants that were customers of a landfill alleging toxic tort exposure injuries and reduced property values. The case management order required the plaintiffs to offer specific proof regarding their alleged exposure, reports of physicians regarding causation and specific information substantiating each claim of property damage. Plaintiffs could not satisfy the burden imposed by the order. The case was eventually dismissed.

The plaintiffs in this multidistrict litigation ("MDL") are spread throughout the United States. One group of defendants in some or all of the cases are Actavis Totowa, LLC ("Actavis Totowa"), Mylan Bertek Pharmaceuticals, Inc., UDL Laboratories, Inc., Actavis, Inc., and Actavis Elizabeth, Inc.. Plaintiffs allege these defendants manufactured, marketed, tested, promoted, sold and/or distributed Digitek® ("Digitek®" or "Digoxin" interchangeably). Two other defendants, Mylan, Inc. and Mylan Pharmaceuticals, Inc., are alleged to have marketed, promoted, sold and/or distributed Digoxin. Mylan Pharmaceuticals, Inc., is also alleged to have distributed Digitek® through its affiliates, Mylan Bertek Pharmaceuticals, Inc. and UDL Laboratories, Inc..

Digitek® is the brand-name of a cardiac glycoside, a compound affecting the myocardium of the heart. The drug is widely used to treat various heart conditions, including atrial fibrillation, atrial flutter, and heart failure that are uncontrolled by other medications. The United States Food and Drug Administration ("FDA") approved the drug with a certain level of the active ingredient, in the following dosages: (1) Digitek® (digoxin tablets, USP) 0.125mg, and (b) Digitek® (digoxin tablets, USP) 0.250 mg. The approved quantities are important because Digitek® has a narrow therapeutic index. Specifically, there is a limited margin between effectiveness and toxicity. An excessive dose of the active ingredient can result in serious health problems and death.

The plaintiffs allege that some of the Digitek® at issue in this action was, among other things, designed and manufactured at a plant in Little Falls, New Jersey ("Little Falls facility"), owned by one or more of the defendants. On or about August 15, 2006, the FDA issued a letter warning to the defendants through Actavis Totowa, LLC, for failing to file periodic safety reports from the Little Falls facility ("August 2006 Warning Letter"). The FDA cautioned that the defendants, through Actavis Totowa, LLC, had violated federal adverse medical event reporting

obligations, marketed drugs without proper clearance, and caused at least twenty-six (26) adverse drug experiences ("ADEs") by failing to submit periodic safety reports.

On or about February 1, 2007, the FDA issued a Revised Warning Letter to the defendants through Actavis Totowa ("Revised Warning Letter"). It cited "significant deviations from the current Good Manufacturing Practice ['cGMP'] regulations." The cGMP regulations describe the methods, controls, equipment, and facilities that must be in place for drug manufacturing operations. The Revised Warning Letter informed the defendants of the following:

> Significant deficiencies were found in the operations of your firm's quality control unit, and as a result there is no assurance that many drug products manufactured and released into interstate commerce by your firm have the identity, strength, quality and purity that they purport to possess.

(Master Compl. ¶ 29).

On August 10, 2006, the deviations were presented to Actavis Totowa on an FDA-483 ("List of Inspections"). The Revised Warning Letter also cited deficiencies in the operations of the quality control unit, which included instances where the unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results for drug products. Specifically, according to the Revised Warning Letter:

> Our investigators observed numerous instances where the quality control unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results involving drug products that ultimately were released for distribution into interstate commerce. Additionally, our investigators uncovered out-of-specification test results in laboratory raw data that were not documented in laboratory notebooks, and found that products were released based on retesting without any justification for discarding the initial out-of-specification test results.

(Master Compl. ¶ 31). Other deficiencies were also cited by the FDA in the Revised Warning Letter:

> Your firm's cleaning validation studies were found to be inadequate and, as a result, there was no assurance that equipment is adequately cleaned between the manufacture of different drug products. [21 CFR §211.67(b)] For example: a)

> Cleaning validation was performed for the process trains without evaluating for sample recovery for numerous products, including: . . . Digoxin Tablets, USP, 0.25mg. [W]e are concerned about the quality of drug products that have been released from your facility under the serious lack of cGMP controls found during the inspection. Your response provides no assurance that the records and conditions of manufacture and testing of each such lot of drug products released and marketed by your firm will be evaluated to assure that the released drug products have their appropriate identity, strength, quality and purity.

(Master Compl. ¶ 35).

A Class I Recall of a drug is instituted only when "there is a reasonable probability that the use or exposure to a violative product will cause serious adverse health consequences or death." On or about April 25, 2008, the FDA announced a Class I Recall of all lots of Bertek and UDL Laboratories Digitek® (digoxin) ("recalled Digitek® (digoxin)"). The Class I recall stated, in part, as follows:

> The product is being recalled due to the possibility that tablets with double the appropriate thickness may contain twice the approved level of active ingredient. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. . . . Several reports of illnesses and injuries have been reported.

(Master Compl. ¶ 38).

The plaintiffs allege that the Recalled Digitek® (digoxin) is an adulterated drug, noting specifically as follows:

> The defendants are drug companies, that upon information and belief, engaged in the marketing, design, development, manufacture, production, processing, compounding, formulating, testing, sale, labeling, packaging, dosing, advertising, promotion, supplying, releasing and/or distribution of Digitek® . . . tablets with amounts of the active ingredient that was not consistent among Digitek® . . . tablets and amounts of the active ingredient that was inconsistent with the dose on the Digitek® . . . label.

(*Id.* at 51-53).

The filing of various civil actions in state and federal courts across the country followed the recall, in which plaintiffs claimed injuries from alleged exposure to defectively manufactured

Digitek®. On August 13, 2008, the Judicial Panel on Multidistrict Litigation entered an order establishing an MDL proceeding in this District consolidating federal Digitek® related actions for joint case management. The Master Complaint filed on February, 9, 2009, asserts the following claims: (1) Failure to Warn and Instruct; (2) Manufacturing Defect; (3) Design Defect; (4) Negligence; (5) Negligence *Per Se*; (6) Breach of Implied Warranty; (7) Breach of Express Warranty; (8) Negligent Misrepresentation; (9) Intentional Misrepresentation; (10) Fraud; (11) Constructive Fraud; (12) Violation of the West Virginia Consumer Credit and Protection Act; (13) Other Unfair Trade Practice Act Violations; (14) Wrongful Death; (15) Survival Action; (16) Medical Monitoring; (17) Unjust Enrichment; (18) Medicare MSP Liability; (19) Loss of Consortium.

Defendants now seek the entry of a "limited" *Lone Pine* order requiring plaintiffs to produce an affidavit from a medical expert identifying case-specific evidence of digoxin toxicity as to each plaintiff, with the exception of those actions selected for Group 1. Defendants request that the affidavit either (1) identify the specific portions of the medical records that, to a reasonable degree of medical certainty, constitute case-specific evidence (*e.g.*, medical records that show elevated digoxin levels or references in the record showing a clinical concern about it), or (2) include medical records demonstrating that a treating physician diagnosed digoxin toxicity. The basis for the request is that "a substantial number of cases currently pending in the MDL are not supported by any case-specific evidence of digoxin toxicity." (Defs. Mot. at 1; Defs.' Memo. in Supp. at 2 ("Nonetheless, responses to Requests for Admission served by various Plaintiffs have revealed that many Plaintiffs' counsel had no medical records in their possession when they filed suit that established high digoxin levels. In even more cases (likely over a majority) there is simply no

evidence of digoxin toxicity reflected by the medical records collected to date by a third party collection service since the inception of the lawsuit.").)

Much of the preceding factual development is found in the Master Complaint. In the instant motion, defendants counter the allegations of that master pleading, in part, as follows:

> The recall was initiated after nonconforming tablets were observed in one lot of the 0.125 mg tablets manufactured - Lot 70924A, manufactured in November 2007. The small number of larger-than-normal tablets were observed before shipment of Lot 70924A, and two comprehensive inspections followed. First, the entire lot, consisting of approximately 4.8 million tablets, was visually inspected pursuant to a protocol drafted by the Quality Assurance Department. Actavis discovered a total of 20 (0.00041 %) nonconforming tablets. The lot was then subjected to a second, rigorous sampling inspection, in which no nonconforming tablets were found. Ultimately, Lot 70924A was released for distribution on January 28, 2008, and sent to Mylan Pharmaceuticals, Inc. for distribution in early February 2008. The April 25, 2008 recall included all lots then in distribution, regardless of dose strength, and even though there was no evidence of any other nonconforming tablets.
>
> No Plaintiffs counsel in any Digitek® case in any jurisdiction has produced a double thick tablet or provided test results from a certified lab that a tablet, within the expiry date, was out of specification. Indeed, Plaintiffs' counsel in the New Jersey cases made this admission on the record at a hearing before Judge Harris on March 27, 2009 attached as Exhibit 1. Further, this fact has been discussed at a number of in-chamber conferences with this Court. It has become increasingly clear that the publicity of the recall and aggressive advertising in follow-up to the recall is at the root of this litigation, not actual evidence of ingestion of a defective product.
>
> . . . .
>
> While the record collection process and evaluation described above has been underway, the FDA determined that there is a small likelihood that any recalled Digitek® caused injury to anyone. (*See* July 8, 2009 FDA Letter, attached as Exhibit 10.) *Lone Pine* orders are especially appropriate where a governmental agency determines that causation is unlikely and the risk of injury small.

(*Id.* at 1-2, 8).

Defendants offer a number of additional contentions supporting the requested *Lone Pine* order. First, they assert that they have experienced "significant difficulties and inordinate

delays" in the process of attempting to secure plaintiffs' fact sheets ("PFS") and related discovery.[2] (*Id.* at 3.) Second, they contend that responses to requests for admission "show repeated instances of filings without having any medical records in hand." (*Id.*) Third, they note instances where medical records were in plaintiffs' possession at the time they instituted their civil actions but that the records revealed no elevated or toxic levels of digoxin were involved. Fourth, defendants state as follows:

> [D]epletion of insurance proceeds by defense costs incurred by defending meritless cases is an interest that all parties and this Court should recognize. While Rule 11 is a mechanism available to Defendants, the cost of determining each meritless claim on a case by case basis is staggering. The parties have retained RecordTrak to obtain medical records. To date, RecordTrak has billed Defendants over $75,000 to obtain records and this figure will soon exceed $100,000. As indicated above, many of these records show no digoxin toxicity. Defendants are spending money and resources to evaluate these cases, collect records and analyze records which only ultimately serve to prove that these cases should never have been filed. Absent the entry of a *Lone Pine* order, judicial resources will be expended considering numerous Rule 11 motions filed by Defendants in individual cases addressing the Plaintiffs' basic failure to conduct pre-filing factual investigation.

(*Id.* at 7-8).

In response, plaintiffs assert primarily that a *Lone Pine* order is not explicitly sanctioned by either federal statute or rule and that its use should be confined to those instances when existing procedural devices and remedies have failed. Second, plaintiffs note that *Lone Pine* orders often result in, essentially, a merits determination akin to summary judgment, but without the corresponding protections offered by Rule 56 and the mutual discovery processes found in Rules 26 through 37. Third, plaintiffs offer a number of cases in which they assert that *Lone Pine* orders were refused and note that the orders, when entered, usually come only after protracted discovery,

[2]The PFS process is described more fully within.

by joint agreement between the parties, or when it became clear that plaintiffs' pleadings failed to provide adequate notice to the many defendants involved in some cases. Responding specifically to defendants' contention concerning the FDA's putative determination that there is a small likelihood of Digitek® injury, plaintiffs note as follows:

> [T]he FDA has issued no report and has made no final determination based on any sort of scientific investigation. The so-called "determination" cited by Defendants comes from the FDA's website in which the FDA responds to the myth that "[t]here are quality problems with generic drug manufacturing." Facts and Myths about Generic Drugs (last updated July 10, 2009), http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ ucm167991.htm. The FDA uses the "recent recall of generic digoxin (called Digitek)" as an example of the FDA's "aggressive action" and "active[] engage[ment] with [the manufacturers of Digitek] to ensure that ALL potentially affected lots of Digitek tablets have been recalled." *Id*. The FDA simply uses the Digitek® recall as an example of its own quality enforcement measures. The FDA in no way purports to provide any official determination about the effect of the out of specification tablets that reached the market, but simply says that due to "the lack of reported adverse events . . . [i]n [the FDA's] best judgment . . . harm to patients was very unlikely." *Id*. A website chronicling the FDA's own quality-control efforts that provides no conclusion about the actual effect of the out of specification Digitek® is not an official report that would support the entry of a *Lone Pine* order.

(Pls.' Resp. at 10-11(alterations in original)). Plaintiffs additionally assert (1) that existing Pretrial Orders ("PTO") have resulted in a significant amount of case-specific discovery being provided to defendants, including the PFS and records authorizations, (2) when those PFS are not provided, defendants have availed themselves of the existing mechanisms for correcting deficiencies or seeking Rule 11 sanctions, (3) defendants have not complied with their discovery obligations, and (4) the Master Complaint alleges that sub-therapeutic dosages of Digitek® were manufactured in addition to dosages exceeding approved therapeutic levels, meaning digoxin toxicity records would not end the merits inquiry in defendants' favor.

In reply, defendants assert, among other arguments, that (1) the requested *Lone Pine* order only seeks information that should have been in plaintiffs' counsels' possession as part of the

prefiling investigation requirements imposed by Rule 11, (2) the discovery not produced by defendants will be turned over and will not reveal if any of the individual plaintiffs had either digoxin toxicity or a subtherapeutic level of the drug, (3) if a subtherapeutic dosage claim is made, it must be supported by a physician's affidavit nevertheless, (4) plaintiffs have failed or refused to respond to a number of the justifications offered by defendants in support of the requested order, and (5) a *Lone Pine* order at this stage of the case will discourage future, meritless civil actions being filed that have undergone inadequate prefiling screening by counsel. In sum, defendants assert as follows:

> There are two options to deal with the substantial number of infirmed cases in this MDL: 1) enter a *Lone Pine* order that simply requires Plaintiffs to point to evidence of digoxin overdose or underdose; or 2) require Defendants to continue to expend significant time, money, and personnel resources to collect and analyze medical records in several hundred cases, and then continue the costly Rule 11 procedure under PTO #39 or the costly summary judgment procedure under Rule 56.

(Defs.' Reply at 3, 4).

II.

A *Lone Pine* order is designed to assist in the management of complex issues and potential burdens on defendants and the court in mass tort litigation, essentially requiring plaintiffs to produce a measure of evidence to support their claims at the outset. *See Steering Committee v. Exxon Mobil Corp.*, 461 F.3d 598, 604 n.2 (5th Cir. 2006); *Acuna v. Brown & Root Inc.*, 200 F.3d 335, 340 (5th Cir. 2000) ("*Lone Pine* orders are designed to handle the complex issues and potential burdens on defendants and the court in mass tort litigation."); *McManaway v. KBR, Inc.*, 2009 WL 4061581, at *1 (S.D. Ind. Nov. 20, 2009)("'The basic purpose . . . is to identify and cull potentially meritless claims and streamline litigation in complex cases.'") (quoting *Baker v. Chevron USA, Inc.*, 2007 WL

315346 at *1 (S.D. Ohio 2007); *see also Abrams v. Ciba Specialty Chem. Corp.*, 2008 WL 4710724, at *2 (S.D. Ala. 2008); *Ramos v. Playtex Prod., Inc.*, 2008 WL 4066250, at *5 (N.D. Ill. Aug. 27, 2008); *Abbatiello v. Monsanto Co.*, 569 F. Supp.2d 351, 353 n.3 (S.D.N.Y. 2008); *In re Vioxx Prod. Liab. Litig.*, 557 F. Supp.2d 741, 743 (E.D. La. 2008); *Burns v. Universal Crop Prot. Alliance*, 2007 WL 2811533, at *1 (E.D. Ark. 2007); *Morgan v. Ford Motor Co.*, 2007 WL 1456154, at *1, 7 (D.N.J. May 17, 2007). Some courts have gone so far as to observe that *Lone Pine* orders are used "routinely" in mass tort cases. *In re Vioxx*, 557 F. Supp.2d at 743. As observed in *In re Vioxx*, however, "[i]n crafting a *Lone Pine* order, a court should strive to strike a balance between efficiency and equity." *Id.*

It is of some consequence that no federal rule or statute requires, or even explicitly authorizes, the entry of *Lone Pine* orders. Nevertheless, *Lone Pine* orders have proven useful at times in complex litigation, and the courts citing authority for this type of extraordinary procedure typically rely upon the broad permission bestowed by *Federal Rule of Civil Procedure* 16. *See Acuna*, 200 F.3d at 340 ("In the federal courts, such orders are issued under the wide discretion afforded district judges over the management of discovery under Fed.R.Civ.P. 16."); *McManaway*, 2009 WL 4061581, at *1 ("*Lone Pine* orders are permitted by Rule 16(c) (2)(L) of the Federal Rules of Civil Procedure which provides that a court may take several actions during a pretrial conference, including 'adopting special procedures for managing potentially difficult or protracted actions that may involve complex issues, multiple parties, difficult legal questions, or unusual proof problems....'" Fed. R. Civ. P. 16(c)(2)(L)."); *Ramos v. Playtex Prod., Inc.*, 2008 WL 4066250, at *5 (N.D. Ill. Aug. 27, 2008) (same); *Morgan*, 2007 WL 1456154, at *5-6 (D.N.J. May 17, 2007) (noting, among other provisions, several potentially applicable provisions of Rule 16); 35B C.J.S *Federal Civil Procedure*

§ 911 (2009) ("So-called '*Lone Pine* orders' are . . . issued under the wide discretion afforded district judges over the management of discovery."); 6A Charles A. Wright *et al.*, *Federal Practice and Procedure* § 1525 (2nd ed. 1990).

The propriety of entering a *Lone Pine* order appears to hinge on a number of factors, including (1) the posture of the action, (2) the peculiar case management needs presented, (3) external agency decisions impacting the merits of the case, (4) the availability and use of other procedures explicitly sanctioned by federal rule or statute, and (5) the type of injury alleged by plaintiffs and its cause. *See, e.g.*, *Steering Comm.*, 461 F.3d at 604 n.2 ("Particularly in this case, where the district court has been careful to manage the litigation efficiently through the judicious use of consolidated summary judgments and *other tools such as Lone Pine* orders, we will not second-guess the district court's discretionary judgment that a class action would not provide a superior method of adjudication.") (emphasis added); *McManaway*, 2009 WL 4061581, at *1 ("Hence, '[s]ome courts have entered [*Lone Pine*] orders only after a state or federal agency has issued a report that either provides much of the information called for in the order or undercuts the plaintiffs' claims for personal injuries.'"); *Abrams*, 2008 WL 4710724, at *2 ("[S]ince this case is going to proceed with a test group, the use of a *Lone Pine* order will not advance the goal of focusing the parties' attention and efforts on the efficient resolution of the test case."); 2 Lawrence G. Cetrulo, *Toxic Torts Litigation Guide* § 13:49 ("'*Lone Pine*' orders are most appropriate in those cases where there is a serious issue over what medical condition or disease, if any, can be causally related to the toxic agent exposure alleged by each plaintiff."); Mark J. Carpenter & George W. Ware, *Defending Pesticides in Litigation* § 10:9 (2009) ("Many courts have applied the *Lone Pine* case management approach in complex cases involving product identity and exposure issues.").

The circumstance-specific nature of the decision to enter a *Lone Pine* order is perhaps best illustrated by the following analysis, undertaken by the Honorable Eldon E. Fallon, who presides over *In re Vioxx*, MDL No. 1657. Judge Fallon noted in particular the "advanced stage" of the litigation:

> *Lone Pine* orders may not be appropriate in every case and, even when appropriate, they may not be suitable at every stage of the litigation. For example, in the present case, a *Lone Pine* order may not have been appropriate at an earlier stage before any discovery had taken place since little was known about the structure, nature and effect of Vioxx by anyone other than perhaps the manufacturer of the drug. But this case is no longer in its embryonic stage. It has existed in state courts for over seven years and in this Court for over three years, and much discovery has taken place. In this MDL, the Plaintiffs' Steering Committee ("PSC") has established and organized a document depository to house materials produced by Merck and has made those materials available to Plaintiffs' counsel in individual cases. In total, Merck has produced over 22 million pages of documents. Hundreds of depositions have taken place. This Court has ruled on approximately one thousand pre-trial motions and has reviewed over 500,000 pages of documents claimed to be subject to attorney-client privilege. Monthly status conferences, at which liaison counsel reported on all developments in the case, have been held in open court since the inception of this MDL. Transcripts of these conferences along with all of the Court's pre-trial orders, opinions, forms and notices have been placed on a special website created for this litigation and are accessible by anyone throughout the country. Six bellwether trials have been held in this MDL as well as fourteen other trials in various state courts throughout the country. Although the bellwether trials in this Court involved only Myocardial Infarctions ("MI's"), the discovery undertaken by the PSC was not limited to that malady. For nearly a decade, Plaintiffs' counsel throughout the country have been studying, exploring, and discovering all of the effects of Vioxx on the human body. In this MDL, the PSC did not selectively discover only MI's or strokes, but rather they conducted general discovery on the effects Vioxx may or may not have on individuals. All of this material is and has been available to counsel in the individual cases.

In re Vioxx, 557 F. Supp.2d at 744; Paul D. Rheingold & Laura Pitter, *Lone Pine Orders: An Abused Remedy?*, American Bar Association Section of Litigation, Mass Torts Litigation Committee, *Mass Torts* (Fall 2009) (referring to the decision in *In re Vioxx* and stating that "[e]ntering a *Lone Pine* order was also dictated by circumstances at the windup of litigation rather than as a threshold sorting tool"*)*; *see also In re 1994 Exxon Chemical Plant Fire*, 2005 WL 6252312, at *2 (M.D. La. Apr. 7,

2005) ("Before these suits were filed, *and at least after the many years since filing them*, one would expect that the remaining plaintiffs would have some concrete, factual basis to support their claims."(emphasis added)).

In addition to case posture and management needs, relevant external agency decisions, the availability and use of rule- and statutory-based procedures, and injury type and cause, case complexity and pleading defects are additional factors worth considering in advance of entering a *Lone Pine* order. For example, the *Acuna* case involved "approximately one thousand six hundred plaintiffs suing over one hundred defendants for a range of injuries occurring over a span of up to forty years . . . . [with] [n]either the defendants nor the court . . . on notice from plaintiffs' pleadings as to how many instances of which diseases were being claimed as injuries or which facilities were alleged to have caused those injuries." *Acuna*, 200 F.3d at 340; *see also McManaway*, 2009 WL 061581, at *2 (noting that the *Lone Pine* case itself involved a court determination "that plaintiffs had failed to allege a *prima facie* case in their complaint . . . .").

Overlying all of these factors, however, are the valid concerns expressed by some judges about the untethered use of the *Lone Pine* process:

> A significant criticism of the *Lone Pine* order is that "it gives courts the means to ignore existing procedural rules and safeguards." *Simeone v. Girard City Bd. of Educ.*, 171 Ohio App.3d 633, 872 N.E.2d 344, 350 (Ohio Ct. App. 2007). The Court of Appeals of Ohio went on to warn that "[w]hen the *Lone Pine* order cuts off or severely limits the litigant's right to discovery, the order closely resembles summary judgment, albeit without the safeguards that the Civil Rules of Procedure supply. Furthermore, many *Lone Pine* orders are inconsistently applied, which further confuses their purpose."

McManaway, 2009 WL 4061581, at *2 (noting further that *Lone Pine* orders can be useful devices but that they are not a "substitute for . . . a motion for summary judgment."; *Simeone*, 171 Ohio App.3d at 643, 872 N.E.2d at 352 ("The timeline of this case is of concern because it is apparent that

appellants were not given the full range and benefit of discovery before the *Lone Pine* order was issued. In most of the *Lone Pine* cases we have reviewed in coming to this conclusion, the *Lone Pine* order was issued only after one party was refusing to comply with discovery requests or when the plaintiffs failed to set forth a prima facie claim. These circumstances are not present in this case."). Also, few *Lone Pine* orders have undergone federal appellate scrutiny. Concerns about the potential for misuse of the device have led at least one judge to observe that "[a] *Lone Pine* order should issue only in an exceptional case and after the defendant has made a clear showing of significant evidence calling into question the plaintiffs' ability to bring forward necessary medical causation and other scientific information." *McManaway*, 2009 WL 4061581, at *5; *Morgan*, 2007 WL 1456154, at *7 (noting the propriety of *Lone Pine* orders but observing also that "they are not appropriate in all circumstances" and that "[a]ny discovery must not be one-sided.") (citing *Hines v. Consol. Rail Corp.*, 926 F.2d 262, 272 (3d Cir.1991) and *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 854-55 (3d Cir.1990)).

III.

Regarding the posture of the action, I received the first MDL transfer order on August 13, 2008. Accordingly, this action has not proceeded as far along as some other cases, such as *In re Vioxx*, where *Lone Pine* orders were deemed appropriate.

Regarding the peculiar case management needs presented, and the use of other procedures explicitly sanctioned by federal rule or statute, I have taken a number of measures, with the cooperation of counsel and my fellow judicial officers on the state bench, to put this litigation on

track for a just, speedy, and efficient disposition. Some of these steps are worth noting. First, following preliminary case management efforts, including the appointment of lead and liaison counsel, federal and state coordination efforts, preliminary discovery orders, and various conferences, a case management and scheduling order, referred to as PTO 16, was entered on March 5, 2009. That detailed PTO was designed to address many of the concerns expressed by the defendants in support of the *Lone Pine* request. If that PTO is being violated, as it has in times past, defendants have remedies available to them, some of which are discussed below.

Second, I required the plaintiffs to file a Master Complaint. That document, which has withstood scrutiny under Rule 12(b)(6), has largely eliminated any concerns respecting pleading defects. It recites in detail the bases of liability asserted by the growing number of plaintiffs who have adopted it. Third, as noted, PTO 16 requires that the defendants receive from each plaintiff in this MDL a PFS, which is in essence treated as a formal discovery response. The PFS is governed by the standards applicable to written discovery under Rules 26 through 37 and must be answered essentially without objections. Plaintiffs are also required by PTO 16 to provide authorizations for release of medical records and to reimburse reasonable copying costs, which address some of the expense concerns presented by defendants. Plaintiffs are further required to produce any documents in their or their counsels' possession showing the fact and dates of Digitek® prescriptions, proof the prescriptions were filled, and re-filled, and medical records documenting the alleged injury suffered as a result of ingesting the drug. If a PFS is not timely or substantially completed, sanctions will result. Indeed, an entire subsection of PTO 16 is devoted to the brief, but detailed, process that defendants may use to compel production of the PFS or seek sanctions. The procedure has been used successfully by defendants, and certain plaintiffs have dismissed a number of meritless cases. I have

also used Rule 16 and the same PTO 16 process to begin the process of imposing monetary sanctions when appropriate. Additionally, in those cases where the PFS, while complete, has called into question the prefiling investigation performed by plaintiffs' counsel, defendants have sought sanctions under Rule 11. Both remedies are a further measure to alleviate the expenses defendants assert they have borne as a result of plaintiffs' noncompliance with existing discovery devices.

Given a choice between a "*Lone Pine* order" created under the court's inherent case management authority and available procedural devices such as summary judgment, motions to dismiss, motions for sanctions and similar rules, I believe it more prudent to yield to the consistency and safeguards of the mandated rules especially at this stage in this litigation. Claims of efficiency, elimination of frivolous claims and fairness are effectively being addressed using the existing and standard means. Resorting to crafting and applying a *Lone Pine* order should only occur where existing procedural devices explicitly at the disposal of the parties by statute and federal rule have been exhausted or where they cannot accommodate the unique issues of this litigation. We have not reached that point.

Regarding the impact of external agency decisions, one might properly characterize the setting as a mixed bag. The FDA has recently expressed the view, in a brief, informal Q&A document on its website, that "[i]n . . . [its] best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients [by Digitek] was very unlikely." (Ex. 10 at 2, Defs.' Mot.). The same document, however, along with a number of allegations in the Master Complaint that discuss FDA enforcement efforts at the Little Falls facility, indicates concerns about Actavis' corrective measures and the need for significant involvement by the FDA in the consumer protection process. When viewed together, this

is not a case, like some others, where the regulatory agency has sounded the "all clear."

Regarding the type of injury alleged and its cause, it is likely that substantial and highly contentious causation issues will arise collectively and individually as this action progresses. Indeed, much expert testimony is anticipated in this litigation as to the causal relationship between the allegedly defective Digitek® and the adverse outcomes allegedly suffered by the affected plaintiffs. I recently scheduled a *Daubert* hearing, roughly a year from now, that will aid in final resolution of those issues. It seems unwise to begin addressing causation issues, in a summary-judgment type fashion that defendants surely contemplate, at this somewhat early juncture when those issues might proliferate and become more complex as the case proceeds.

In sum, the factors that often coincide to warrant entry of a *Lone Pine* order are not presented at this time. This is not to say that, at a later point in the litigation, that the need for this type of case management tool within the discretion of the court, might not arise. At this point, however, it has not been shown that this action qualifies as "an exceptional case" justifying the extraordinary relief sought. Accordingly, I **DENY** without prejudice defendants' motion for entry of a *Lone Pine* case management order and supplemental motion modifying requested relief.

The court **DIRECTS** the Clerk to file a copy of this order in 2-08-md-1968 which shall apply to each member Digitek-related case previously transferred to, removed to, or filed in the is district, which includes counsel in all member cases up to and including civil action number 2-10-cv-0017. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be

the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: January 8, 2010

Joseph R. Goodwin, Chief Judge